

REMARKS

This amendment is responsive to the Office Action of January 31, 2005. Reconsideration and allowance of claims 2-15 and 17-39 are requested.

The Office Action

Claims 2-15 and 17-39 stand rejected under 35 U.S.C. § 103 as unpatentable over Kienzle (US 6,285,902) in view of Martinez (US 4,577,629).

The References of Record

The **Kienzle** patent is a substantially cumulative example of the acknowledged prior art. Kienzle discloses a surgical suite in which one finds control computers **121, 124** which are interconnected with a display **122** and a sensor unit **123** which tracks instrumented **129** tools **128**, etc. Kienzle takes the presence of the instrumented tools in the surgical suite as a given. After all, most hospitals have a sterilization facility which cleans and sterilizes used instruments and returns them sterile for use in a subsequent operation. The computers **121, 124** are preprogrammed with all of the software which is necessary for the normal and described functioning of the Kienzle device. There is no suggestion in Kienzle that the software is in any way insufficient or that it must be in any way modified or reloaded to render it operative for its intended purpose for each surgical procedure.

Martinez discloses a non-instrumented surgical instrument which can be thrown away after use.

The Present Application

In the present application, the hospital purchases a surgical kit. This kit includes the pre-sterilized surgical instruments, along with the accessories, appliances, surgical screws, braces, and the like which are necessary to perform a preselected surgical operation. Additionally, the kit includes a digital media which is preprogrammed with the latest version of the image guided surgery software for performing the given surgical procedure, but not other surgical procedures. More specifically, the hospital buys a computer which is preprogrammed with relatively inexpensive minimally functional software and "leases" the latest version of the

additional software which is needed to perform the selected operation and only the selected operation. The cost of the kit includes the seller's cost of creating and maintaining the various software packages. The price also reflects the price for reprocessing or replacing the surgical instruments, as may be appropriate.

After the surgical procedure, the digital medium is deactivated, such that it is limited to a single usage. The next time the self-same operation is performed, even if the same operation is performed on two patients back-to-back, a new surgical kit is purchased. In this way, the cost reflects the actual usage of the software and hospitals (or insurance companies) do not pay for software which they do not use. This is distinct from the conventional prior surgical suite in which the computer is preprogrammed with all potential image guided surgery procedures, including procedures which the hospital may never perform during the life of the equipment or software.

Examiner Discussion

The applicants thank Examiner Jung for the kind courtesy of a telephone conference during the week of February 7, 2005, in which the Examiner expanded upon and explained the rationale of his rejection in greater detail. After discussing claim 5, in which the digital medium is deactivated after the surgical procedure, the applicants understood that a Request for Reconsideration might be favorably received. Other claims are amended herein in light of the discussions.

The Claims Distinguish Patentably Over the References of Record

Claim 2 calls for an image-guided surgery system which includes a computer preprogrammed with a portion of image guided surgery software that provides minimal user functionality. In Kienzle, there is no suggestion that the computers 121, 124 are programmed with anything less than full image guided surgery functionality. If Kienzle's computers were not programmed with full functionality, Kienzle would be inoperative for its intended function.

Claim 2 also calls for a kit which includes instrumented surgical tools and a digital medium which are removably disposed in an openable, transportable case. The digital medium includes application specific software which upgrades the image

guided surgery software to facilitate performance of the preselected surgical procedure. Kienzle makes no suggestion of shipping a digital medium preprogrammed for a preselected procedure and the tools for the same preselected surgical procedure in a common case. Martinez does not overcome any of these shortcomings of Kienzle. Accordingly, it is submitted that **claim 2 and claims 3-4 dependent therefrom** distinguish patentably and unobviously over the references of record.

Claim 5 calls for an image guided surgery system which includes a digital medium with application specific software and a means for deactivating or encrypting the digital medium against reuse. Kienzle makes no suggestion that the software in computers 121 or 124 should in any way be deactivated or encrypted at the end of a surgical procedure. Moreover, Kienzle provides no means for performing this function. Martinez does not cure this shortcoming. Accordingly, it is submitted that **claim 5 and claims 6 and 12-15 dependent therefrom** distinguish patentably and unobviously over the references of record.

Claim 7 calls for a kit which includes a portable, openable housing to which an identifying label for a preselected surgical procedure is attached. Tools and accessories for the surgical procedure, user output devices, and a digital medium with software specific to the preselected surgical procedure are all disposed in the housing. Kienzle makes no suggestion of a kit in which these various tools, accessories, and software-carrying digital medium, all specific to a preselected surgical procedure are disposed. Martinez fails to cure or even address these shortcomings of Kienzle. Accordingly, it is submitted that **claim 7 and claim 8 dependent therefrom** distinguish patentably and unobviously over the references of record.

Claim 9 calls for a disposable kit which includes tools and a digital medium, both of which are packaged in a common shipping unit. Kienzle neither discloses nor provides any motivation for including surgical tools and a digital medium in a common unit. Indeed, the computers of Kienzle appear to be fully programmed. Kienzle in no way suggests or provides any motivation for shipping software in conjunction with the surgical tools to the imaging suite. Even if one were to periodically upgrade the software of Kienzle, it is submitted that Kienzle provides no motivation to make such upgrades a part of his surgical tool package. Martinez

fails to cure this shortcoming of Kienzle. Accordingly, it is submitted that **claim 9** distinguishes patentably and unobviously over the references of record.

Claim 10 calls for an image guided surgery system including a software integrated, one time use kit. The kit includes a shipping case in which surgical tools and a digital medium are removably received. The digital medium is preprogrammed with software describing dimensions of each of the tools, probes, guides, and any other instrumented accessories contained in the kit. Kienzle makes no suggestion that its instrumented surgical tools should be disposed in a common case with a digital medium programmed with a description of said tools. Martinez fails to cure this shortcoming of Kienzle. Accordingly, it is submitted that **claim 10** distinguishes patentably and unobviously over the references of record.

Claim 11 calls for a surgery system which includes a computer and software integrated kits. Each kit includes surgical tools and a programmed digital medium which are removably disposed in a common case. Kienzle fails to teach or fairly suggest enclosing the surgical tools and a digital medium in a common case. Moreover, claim 11 calls for the digital medium to be preprogrammed with software of 3D virtual representations, images, or other information regarding the surgical tools and any accessories, implants, and associated hardware which is contained in the kit. Kienzle makes no suggestion of a software medium programmed regarding the surgical tools which are contained in the same kit. Accordingly, it is submitted that **claim 11** distinguishes patentably and unobviously over the references of record.

Claim 20 calls for removing digital medium from a kit and inserting it into a computer at the surgical site, and augmenting the software on the computer with the software from the digital medium. Claim 20 further calls for deactivating or encrypting the digital medium against reuse after the surgical procedure. Kienzle makes no suggestion of augmenting the software on the computers **121** and **124**, much less of deactivating the digital medium carrying the augmenting software against reuse. Martinez fails to overcome or even address these shortcomings of Kienzle. Accordingly, it is submitted that **claim 20 and claims 17-19, 21, and 22 dependent therefrom** distinguish patentably and unobviously over the references of record.

Claim 23 calls for a surgical method in which a kit that includes surgical tools and accessories and a digital medium is provided. At the surgical site, the

digital medium and the surgical tools and accessories are removed from the kit. Kienzle fails to teach or fairly suggest a kit which includes both surgical tools and a digital medium, both of which are removed from the kit at a surgical site. By distinction, the Kienzle software appears to be resident at the surgical site, and while it must have arrived sometime and may have been upgraded from time-to-time, there is no suggestion of a kit which provides both the surgical tools and the software together in a common kit. Accordingly, it is submitted that **claim 23 and claims 24-29 dependent therefrom** distinguish patentably and unobviously over the references of record.

Claim 30 calls for a surgical kit that includes a housing having an identification of a surgical procedure to be performed using the kit. Surgical tools, medical appliances, and digital medium, all of which are used in the identified surgical procedure, are removably disposed in the housing. Kienzle makes no suggestion of a kit, much less a kit that contains the enumerated items. Martinez fails to cure there shortcomings of Kienzle. Accordingly, it is submitted that **claim 30** distinguishes patentably and unobviously over the references of record.

Claim 31 is directed to an image-guided surgery system that includes a set of surgical tools and a processor which is preprogrammed with less than all of the software for image guided surgery. By distinction, Kienzle makes no suggestion that computers **121, 124** contain any less than all of the software needed to render Kienzle operative for its intended function.

Claim 31 further calls for a digital medium which is preprogrammed with the remaining portion of the software. Kienzle makes no suggestion of such an additional digital medium. Accordingly, it is submitted that **claim 31 and claims 32-37 dependent therefrom** distinguish patentably and unobviously over the references of record.

Claim 33 further calls for a deactivator which deactivates the digital medium against reuse at the end of an image guided surgical procedure. Kienzle makes no suggestion of any deactivator which deactivates the software in computers **121, 124** to render the Kienzle system inoperative for its intended function. Martinez does not cure this shortcoming of Kienzle. Accordingly, it is submitted that **claim 33** distinguishes patentably and unobviously over the references of record.

Claim 38 calls for a single use digital medium and a means for disabling the software on the medium from being reused. Kienzle makes no suggestion of any means for disabling the software in computers 121 and 124 against being used again for the attendant purpose of Kienzle. Martinez fails to cure this shortcoming of Kienzle. Accordingly, it is submitted that **claim 38** distinguishes patentably and unobviously over the references of record.

Claim 39 calls for deactivating or encrypting a digital medium against reuse. Deactivating the digital medium which carries the software of computer 121 or 124 of Kienzle would render the Kienzle system inoperative for its intended purpose. Martinez fails to cure this shortcoming of Kienzle. Accordingly, it is submitted that **claim 39** distinguishes patentably over the references of record.

In the discussions with the Examiner, the Examiner noted that **claim 39**, which is not specific to a surgical method, might be separately classified from the other claims and suggested that a Restriction Requirement might be proper. Upon allowance of the remaining claims, the applicants are amenable to cancelling claim 39 from the present application without prejudice to filing a timely divisional application to continue the prosecution of this claim.

Telephone Interview

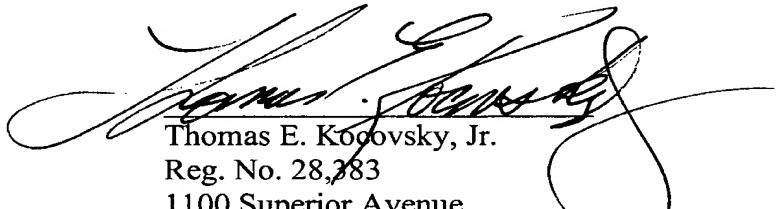
The Examiner is invited to telephone the undersigned at the number listed below to discuss the claims, the present amendment, or possible Examiner's Amendments which potentially place the present application in condition for allowance.

CONCLUSION

For the reasons set forth above, it is submitted that claims 2-15 and 17-39 distinguish patentably and unobviously over the references of record. An early allowance of all claims is requested.

Respectfully submitted,

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